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PPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.	
09/579,680	05/26/2000	Blake R. Pepinsky	BIIJ-P02-067	8259	
28120	7590 08/19/2003				
ROPES & GRAY LLP ONE INTERNATIONAL PLACE BOSTON, MA 02110-2624		EXAMINER			
			O HARA, E	O HARA, EILEEN B	
			ART UNIT	PAPER NUMBER	
	•	-	1646		
			DATE MAILED: 08/19/2003	DATE MAILED: 08/19/2003	

Please find below and/or attached an Office communication concerning this application or proceeding.

پ در س						
	Application N .	on N . Applicant(s)				
·	09/579,680	PEPINSKY ET AL.				
Office Action Summary	Examiner	Art Unit				
	Eileen O'Hara	1646				
The MAILING DATE f this communication appears n the c ver sheet with the correspondence address Period f r Reply						
A SHORTENED STATUTORY PERIOD FOR REF THE MAILING DATE OF THIS COMMUNICATION  - Extensions of time may be available under the provisions of 37 CFR after SIX (6) MONTHS from the mailing date of this communication.  - If the period for reply specified above is less than thirty (30) days, a right of No period for reply is specified above, the maximum statutory perions  - Failure to reply within the set or extended period for reply will, by stated to the communication of	N. 1.136(a). In no event, however, may a repeply within the statutory minimum of thirty od will apply and will expire SIX (6) MONT tute, cause the application to become ABA	oly be timely filed  (30) days will be considered timely.  HS from the mailing date of this communication.  NDONED (35 U.S.C. § 133).				
Status	0.44 0.000					
1) Responsive to communication(s) filed on 25	<del>-</del>					
<u> </u>	This action is non-final.					
3) Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under Ex parte Quayle, 1935 C.D. 11, 453 O.G. 213.  Disposition of Claims						
4)⊠ Claim(s) <u>See Continuation Sheet</u> is/are pen	iding in the application.					
4a) Of the above claim(s) is/are withdrawn from consideration.						
6)⊠ Claim(s) 106 and 110 is/are rejected.						
7) Claim(s) is/are objected to.	•					
8) Claim(s) are subject to restriction and	d/or election requirement.					
Application Papers						
9) The specification is objected to by the Exami						
10) $\boxtimes$ The drawing(s) filed on <u>22 January 2002</u> is/are: a) $\boxtimes$ accepted or b) $\square$ objected to by the Examiner.						
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).						
11) The proposed drawing correction filed on is: a) approved b) disapproved by the Examiner.						
If approved, corrected drawings are required in reply to this Office action.						
12) The oath or declaration is objected to by the Examiner.						
Priority under 35 U.S.C. §§ 119 and 120						
13) Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).						
a) All b) Some * c) None of:						
	1. Certified copies of the priority documents have been received.					
2. Certified copies of the priority documents have been received in Application No						
<ul> <li>3. Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).</li> <li>* See the attached detailed Office action for a list of the certified copies not received.</li> </ul>						
14) Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).						
a) ☐ The translation of the foreign language provisional application has been received.  15)☑ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.						
Attachment(s)	. ,	. <del>.</del>				
1) Notice of References Cited (PTO-892) 2) Notice of Draftsperson's Patent Drawing Review (PTO-948) 3) Information Disclosure Statement(s) (PTO-1449) Paper No(s)	5) Notice of Inf	ummary (PTO-413) Paper No(s) formal Patent Application (PTO-152)				
S. Palent and Trademark Office						

Continuation Sh t (PTO-326)

Applicati n No. 09/579,680

Continuation of Disposition of Claims: Claims pending in the application are 1-10,14,15,28-31,40-42,46,48,50,53,56,57,63-68,71,87-89 and 92-110.

	Application N . 09/579,680	Applicant(s) Pepinsky et al.				
Notice to Comply						
Notice to Comply	Examiner	Art Unit				
NOTICE TO COMPLY WITH DECL	Eileen B. O'Hara	1646				
NOTICE TO COMPLY WITH REQUIREMENTS FOR PATENT APPLICATIONS CONTAINING NUCLEOTIDE SEQUENCE AND/OR AMINO ACID SEQUENCE						
DISCLOSURES						
Applicant must file the items indicated below within the time period set the Office action to which the Notice is attached to avoid abandonment under 35 U.S.C. § 133 (extensions of time may be obtained under the provisions of 37 CFR 1.136(a)).						
The nucleotide and/or amino acid sequence disclosure contained in this application does not comply with the requirements for such a disclosure as set forth in 37 C.F.R. 1.821 - 1.825 for the following reason(s):						
1. This application clearly fails to comply with the requirements of 37 C.F.R. 1.821-1.825. Applicant's attention is directed to the final rulemaking notice published at 55 FR 18230 (May 1, 1990), and 1114 OG 29 (May 15, 1990). If the effective filing date is on or after July 1, 1998, see the final rulemaking notice published at 63 FR 29620 (June 1, 1998) and 1211 OG 82 (June 23, 1998).						
2. This application does not contain, as a separate part of the disclosure on paper copy, a "Sequence Listing" as required by 37 C.F.R. 1.821(c).						
3. A copy of the "Sequence Listing" in computer readable form has not been submitted as required by 37 C.F.R. 1.821(e).						
4. A copy of the "Sequence Listing" in computer readable form has been submitted. However, the content of the computer readable form does not comply with the requirements of 37 C.F.R. 1.822 and/or 1.823, as indicated on the attached copy of the marked -up "Raw Sequence Listing."						
5. The computer readable form that has been filed with this application has been found to be damaged and/or unreadable as indicated on the attached CRF Diskette Problem Report. A Substitute computer readable form must be submitted as required by 37 C.F.R. 1.825(d).						
6. The paper copy of the "Sequence Listing" is not the same as the computer readable from of the "Sequence Listing" as required by 37 C.F.R. 1.821(e).						
☑ 7. Other: see attached office action						
Applicant Must Provide:  ☑ An initial or substitute computer reada	ble form (CRF) copy of the "Sequ	ence Listing".				
oxtimes An initial or substitute paper copy of thinto the specification.	e "Sequence Listing", as well as a	an amendment directing its entry				
A statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d).						
For questions regarding compliance	e to these requirements, ple	ase contact:				
For Rules Interpretation, call (703) 308-4216						
For CRF Submission Help, call (703) 308-4212						
PatentIn Software Program Support Technical Assistance703-287-0200						
To Durchase Detentin Software						

PLEASE RETURN A COPY OF THIS NOTICE WITH YOUR REPLY

#### **DETAILED ACTION**

1. Claims 1-10, 14, 15, 28-31, 40-42, 46, 48, 50, 53, 56, 57, 63-68, 71, 87-89 and 92-110 are pending in the instant application. Claims 19, 22-27, 34, 35, 39, 47, 49, 60, 61 and 90-92 have been canceled as requested by Applicant in Paper Number 22, filed May 27, 2003.

## Withdrawal of Finality

2. The finality is hereby withdrawn and prosecution is re-opened because of new grounds of rejection under 35 USC § 101 (see rejections below).

#### Supplemental Oath Required

3. A supplemental oath is required because the citizenship of Alphonse Galdes was corrected by hand but not initialed.

#### Specification

- 4.1 The examiner has amended the specification to correct the numbering of the Tables, because the first Table presented was labeled Table 2. All references to the tables in the specification have also been renumbered correspondingly.
- 4.2 The disclosure is objected to because of the following informalities: there are blanks on page 78, lines 13, 14 and 16, page 79, line 7, and page 81, line 10, all corresponding to SEQ ID NOS.

Appropriate correction is required.

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# Sequence Compliance

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5. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the reason(s) set forth on the attached Notice To Comply With Requirements For Patent Applications Containing Nucleotide Sequence And/Or Amino Acid Sequence Disclosures. Applicant must comply with the requirements of the sequence rules (37 CFR 1.821 - 1.825) before the application can be examined under 35 U.S.C. §§ 131 and 132.

Applicant is given the statutory time from the mailing date of this communication within which to comply with the sequence rules, 37 CFR 1.821 - 1.825. Failure to comply with these requirements will result in ABANDONMENT of the application under 37 CFR 1.821(g). Extensions of time may be obtained by filing a petition accompanied by the extension fee under the provisions of 37 CFR 1.136(a). Direct the reply to the undersigned. Applicant is requested to return a copy of the attached Notice to Comply with the reply.

In particular, there are sequences on pages 78, 79 and 81 that are not present in the sequence listing. M.P.E.P. 2422.03 states: "37 CFR 1.821(c) requires that applications containing nucleotide and/or amino acid sequences that fall within the above definitions, contain, as a separate part of the disclosure on paper or compact disc, a disclosure of the nucleotide and/or amino acid sequences, and associated information, using the format and symbols that are set forth in 37 CFR 1.822 and 37 CFR 1.823. This separate part of the disclosure is referred to as the "Sequence Listing." The "Sequence Listing" submitted pursuant to 37 CFR 1.821(c), whether on paper or compact disc, is the official copy of the "Sequence Listing." 37 CFR 1.821(c) requires that each sequence disclosed in the application appear separately in the "Sequence Listing," with each sequence further being assigned a sequence identification number, referred to as "SEQ ID NO."

Applicant needs to provide a substitute computer readable form (CRF) copy of a "Sequence Listing" which includes all of the sequences recited in the claims and specification of the instant application which are encompassed by these rules, a substitute paper copy of that "Sequence Listing", an amendment directing the entry of that paper copy into the specification, and a statement that the content of the paper and computer readable copies are the same and, where applicable, include no new matter, as required by 37 C.F.R. §§ 1.821(e) or 1.821(f) or 1.821(g) or 1.825(b) or 1.825(d). The instant specification will also need to be amended so that it complies with 37 C.F.R. § 1.821(d) which requires a reference to a particular sequence identifier (SEQ ID NO:) be made in the specification and claims wherever a reference is made to that sequence. For rules interpretation Applicant may call (703) 308-1123. See M.P.E.P. 2422.04.

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### Withdrawn Rejections

6. The rejection of claims under obviousness type double patenting is withdrawn in view of Applicants' terminal disclaimer.

#### **Double Patenting**

A rejection based on double patenting of the "same invention" type finds its support in the language of 35 U.S.C. 101 which states that "whoever invents or discovers any new and useful process ... may obtain a patent therefor ..." (Emphasis added). Thus, the term "same invention," in this context, means an invention drawn to identical subject matter. See *Miller v. Eagle Mfg. Co.*, 151 U.S. 186 (1894); *In re Ockert*, 245 F.2d 467, 114 USPQ 330 (CCPA 1957); and *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970).

A statutory type (35 U.S.C. 101) double patenting rejection can be overcome by canceling or amending the conflicting claims so they are no longer coextensive in scope. The filing of a terminal disclaimer <u>cannot</u> overcome a double patenting rejection based upon 35 U.S.C. 101.

7. Claims 106 and 110 are rejected under 35 U.S.C. 101 as claiming the same invention as that of claims 9 and 26 of prior U.S. Patent No. 6,444,793. This is a double patenting rejection.

#### Conclusion

- 8.1 1-10, 14, 15, 28-31, 40-42, 46, 48, 50, 53, 56, 57, 63-68, 71,87-89, 93-105 and 107-109 are allowed.
- 8.2 Claims 106 and 110 are rejected.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Eileen B. O'Hara, whose telephone number is (703) 308-3312. The examiner can normally be reached on Monday through Friday from 10:00 AM to 6:30 PM.

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If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Yvonne Eyler can be reached at (703) 308-6564.

Official papers Before Final filed by RightFax should be directed to (703) 872-9306.

Official papers After Final filed by RightFax should be directed to (703) 872-9307.

Official papers filed by fax should be directed to (703) 308-4242.

Any inquiry of a general nature or relating to the status of this application should be directed to the Group receptionist whose telephone number is (703) 308-0196.

Eileen B. O'Hara, Ph.D.

Patent Examiner

VONNE EYLER, PH.D SUPERVISORY PATENT EXAMINER TECHNOLOGY CENTER 1600